510(k) Summary (21 CFR Part 807.92)

Product: Rapid Amphetamine, Benzodiazepines, Cocaine, THC, Opiate, Methamphetamine and Phencyclidine Test Strips and DOA Multiple Drug Test Cards (up to six tests).

Name of Manufacturer: Rapid Diagnostics, Inc. 1429 Rollins Road, Burlingame, California, USA

Principle: The Rapid Drug tests are based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for antibody binding between drug conjugate and free drug which may be present in the urine specimen being tested.

When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 1000 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

Intended Use: The Rapid Drug tests are immunochromatography based one step in vitro test. It is designed for qualitative determination of amphetamine, benzodiazepines, cocaine, THC, opiate, methamphetamine and phencyclidine in human urine specimens above the following cut-off level:

Amphetamine	1000 ng/ml
Benzodiazepines	300 ng/ml
Cocaine	300 ng/ml
THC	50 ng/ml
Opiate	300 ng/ml
Methamphetamine	1000 ng/ml
Phencyclidine	25 ng/ml

Performance: The studies performed are listed below: sensitivity, precision, reproducibility, accuracy (comparison study of clinical urine specimens), product and specimen stability, interference and specificity. Both urine control specimen and clinical urine specimen were tested to evaluate the safety and effectiveness of Rapid Drug Test Panels. The results of performance characteristics demonstrate the Rapid Drug Tests to be substantially equivalent to the SureStep Drugs Screen Panels which received 510k approvals.



Food and Drug Administration 2098 Gaither Road Rockville MD 20850

APR 2 0 2001

Mr. Charles Yu President Rapid Diagnostics, Inc. 1429 Rollins Road Burlingame, CA 94010

Re: 510(1

510(k) NUMBER: K003809

Trade/Device Names: Rapid Amphetamine Test Strip

Rapid Benzodiazepines Test Strip

Rapid Cocaine Test Strip Rapid THC Test Strip Rapid Opiates Test Strip

Rapid Methamphetamine Test Strip Rapid Phencyclidine Test Strip

Rapid DOA-2, DOA-3, DOA-4, DOA-5 and DOA-6

Multiple Test Panels

Regulation Number: 862.3100, 862.3610, 862.3170, 862.3870, 862.3250, 862.3650

Regulatory Class: II

Product Code: DKZ, DJC, JXM, LDJ, DIO, DJG

Dated: March 20, 2001 Received: March 22, 2001

Dear Mr. Yu:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.

Director

Division of Clinical Laboratory Devices

Steven Dutman

Office of Device Evaluation

Center for Devices and Radiological Health

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510(k) Number (i	f known):	K003809			
Device Name:	Rapid Amp	hetamine Test Strip			
Indications For U	lse:				
The Rapid AM for qualitative level of 1000 na	determinatio	immunochromatograp n of amphetamine an	hy based one ste d in human urin	p in vitro te e specimen:	est. It is designed s above a cut-off
The test kit is is is not intended	used to obtain for over the o	ı a visual, qualitative ı counter sale to lay pers	result and is intensions.	ided for pro	ofessional use. It
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Prescription Use	100)	OR	Over-The-Co	unter Use	
(Per 21 CFR 801	.109)		(0	Optional Forn	nat 1-2-96)

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510(k) Number (if	known):				
Device Name:	Rapid Benzodiazep	ines Test Strip			
Indications For Us	se:				
for qualitative of	Test is an immuno letermination of ben level of 300 ng/ml.	chromatograp zodiazepines a	hy based one step in and its metabolites in	ı vitro te ı human	st. It is designed urine specimens
The test kit is u is not intended	sed to obtain a visua for over the counter	al, qualitative i sale to lay pers	result and is intende sons.	d for pro	ofessional use. It
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Prescription Use (Per 21 CFR 801.	109)	OR	Over-The-Count		 nat 1-2-96)

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510(k) Number (if k	nown):			
Device Name:	Rapid Cocaine Test Stri	p		
Indications For Use	;			
for qualitative	Test is an immunochro determination of coca a cut-off level of 300 ng	ine's metaboli	ased one step in vit te, benzoylecgonir	ro test. It is designed ne, in human urine
The test kit is use is not intended for	ed to obtain a visual, q or over the counter sale	ualitative result to lay persons.	and is intended fo	r professional use. It
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Prescription Use (Per 21 CFR 801.1)	09)	OR	Over-The-Counter U	se

The Rapid THC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC and its metabolites in human urine specimen. The present of 11-nor-Δ²-COOH in human urine above a cut-off level of 50 ng/ml can be detected. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons. (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)				f	Page	of
The Rapid THC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC and its metabolites in human urine specimen. The present of 11-nor-Δ²-COOH in human urine above a cut-off level of 50 ng/ml can be detected. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons. (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)	510(k) Number (i	f known):				
The Rapid THC Test is an immunochromatography based one step in vitro test. It is designed for qualitative determination of THC and its metabolites in human urine specimen. The present of 11-nor-A2-COOH in human urine above a cut-off level of 50 ng/ml can be detected. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons. (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use OR Over-The-Counter Use	Device Name:	Rapid THC Test Str	ip			
for qualitative determination of THC and its metabolites in human urine specimen. The present of 11-nor-Δ²-COOH in human urine above a cut-off level of 50 ng/ml can be detected. The test kit is used to obtain a visual, qualitative result and is intended for professional use. It is not intended for over the counter sale to lay persons. [Please Do Not Write Below this line-continue on Another Page IF Needed) Concurrence of CDRH, Office of Device Evaluation (ODE) Prescription Use	Indications For U	se:				
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510(k) Number (if	known):			
Device Name:	Rapid Opiates Test Str	ip		
Indications For Us	se:			
	iates Test is an immu qualitative determination presence of Opiates in	an at Unigles	and its metaboutes	III Human arme
The test kit is u is not intended	ised to obtain a visual, o for over the counter sale	qualitative resu e to lay persons	lt and is intended for p s.	rofessional use. It
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510(k) Number (if	known):				
Device Name:	Rapid Methamphetamine	Test Strip		·	
Indications For Us	e:				
designed for a	THAMP Test is an immurualitative determination of above a cut-off level of 100	of methampi	graphy based hetamine and	one step i its metal	n vitro test. It is polites in human
The test kit is u	ised to obtain a visual, qua for over the counter sale to	ilitative resu o lay persons	lt and is inten s.	ded for pr	ofessional use. It
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510(k) Number (i	if known):		_ 		
Device Name:	Rapid Phencyclid	ine Test Strip			
Indications For U	Jse:				
for qualitative	P Test is an immun determination of P e above a cut-off lev	hencyclidine in h	iuman urine specii	n vitro tes nen. The p	t. It is designed presence of PCP
The test kit is is not intended	used to obtain a vis I for over the counte	ual, qualitative r er sale to lay pers	esult and is intend ons.	ed for pro	fessional use. It
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510(k) Number	(if known):			
Device Name:	Rapid DOA-2, DOA-3,	DOA-4, DOA-5	and DOA-6 Multiple	Test Panels
Indications For		_		ston in vitro test It
is designed fo	DOA Test Panels are the in qualitative determination	of drug of abu	se substance in num	an urme specimen
The following cot-off concer	g component strips are used ntration level of each strip a	l for the combiner listed below	nations of DOA mult:	tiple test panels, the
	Amphetamine	1000	ng/ml	
F	Benzodiazepines	300	ng/ml	
	Cocaine	300	ng/ml	
	THC	50	ng/ml	
	Opiates	300	ng/ml	
	Methamphetamine	1000	ng/ml	
	Phencyclidine	25	ng/ml	
(Division Division	le test kit is used to obtuse. It is not intended for our significant statement of Clinical statement of SSCI	ver the counter	r sale to lay persons.	
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